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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,567	05/12/2005	Jean-Francois Biegun	CAC.P0046	6534
7590 Edward G Greive Renner Kenner Greive Bobak Taylor & Weber Fourth Floor First National Tower Akron, OH 44308-1456			EXAMINER WOODALL, NICHOLAS W	
			ART UNIT 3775	PAPER NUMBER
			MAIL DATE 10/16/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/534,567

**Applicant(s)**

BIEGUN ET AL.

**Examiner**

Nicholas Woodall

**Art Unit**

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12, 13 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 13 and 15-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI-108)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_



**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/04/2008 has been entered.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 22 states ...said plastic material is hard enough for this removal and wears out after a single use.... The examiner would like to note that the specification does not support these limitations regarding the cutting guide embodiment of the device. The plastic portions of the cutting guide are not being used to cut the bone, but are used to house metal inserts that line the cutting slots to guide and support the blades being used to cut the bone. Therefore, the examiner is unable to

understand how the plastic wears out after a single use since no portion of the plastic material is being used to actually remove or cut the bone in this embodiment. Therefore, the claim adds new matter that is not described in the specification. Claim 23 states ...that it is hard enough for said attack and wears out after a single use.... The specification discloses two embodiment of an acetabular drill (see page 6 lines 16-20). The first embodiment includes a hemispherical head made from plastic that includes metal blades protruding from the head for cutting/attacking the bone. The second embodiment replaces the metal blades with plastic ribs for cutting/attacking the bone. Claim 23 appears to be directed the first embodiment because claim 23 states ...and at least one metallic blade embedded in said plastic material protruding from said head and in the shape of at least one rib for attacking a hip bone, wherein said plastic material ... so that it is hard enough for said attack and wears out after a single use.... The plastic portion is not used to cut/attack the bone in the embodiment comprising a metallic insert. Therefore, the plastic portion would not wear out because the plastic portion is not being used to cut/attack the bone. Therefore, the claim adds new matter that is not described in the specification.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 22 fails to clearly point out and distinctly claim the subject matter in which the applicant regards as the invention. Claim 22 is directed to a gutting guide, wherein the body is made from a plastic that includes embedded metallic inserts along the cutting slots to support and guide cutting blades inserting through the cutting slots. The specification does not support the plastic body being used to remove the bone and therefore the plastic body would not wear out after a single use as required by the claim. Therefore, the examiner will interpret the claim without the limitation requiring the plastic to wear out after a single use as supported by the specification for examination purposes.

7. Claim 23 fails to clearly point out and distinctly claim the subject matter in which the applicant regards as the invention. Claim 23 is directed to an acetabular drill having a hemispherical head made from plastic including at least one metallic blade in the shape of at least one rib protruding from the head to attack/cut the bone. The specification does not support the plastic head of the drill being used to remove the bone, since that is the purpose of the metal inserts, and therefore the plastic body would not wear out after a single use as required by the claim. Therefore, the examiner will interpret the claim without the limitation requiring the plastic to wear out after a single use as supported by the specification for examination purposes.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 15, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Geisser (U.S. Patent 5,454,815).

Geisser discloses a device made from a plastic material including a carbon fiber reinforcing insert completely embedded within the plastic material, such as polyamides (column 3 lines 7-12), that come into contact with a bone to rasp the bone. The plastic material is hard enough to rasp the bone and wears out after a single use (column 1 lines 29-35; column 1 lines 40-67), wherein the plastic is inherently capable deteriorating when put into an autoclave set to at least 137 degrees Celsius. The examiner would like to note that Geisser discloses the device can be made from polyamides, which is a specific material listed by the applicant in the specification (page 3 lines 7-9). Therefore, the device inherently has the capability of deteriorating at 137 degrees Celsius, since they are made from the same materials. Also, the examiner would like to note that Geisser discloses that all rasps dull during use and that any dullness is a considerable disadvantage suggesting that all rasps wear out after a single use causing significant problems such as longer operation time and overheating (see column 1 lines 29-35). Geisser then discloses his invention directed to a single use plastic rasp that will be discarded after use to alleviate the need for sterilization and cleaning (see column 1 lines 61-64). Therefore, the examiner believes Geisser clearly discloses a device that wears out after a single use and is then discarded.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisser (U.S. Patent 5,454,815) in view of Judd (U.S. Patent 1,396,934).

Geisser discloses the invention as claimed except for the insert being made from a metal. Geisser discloses a device made from a plastic material including a carbon fiber reinforcing insert completely embedded within the plastic material in order to reinforce the plastic material. Judd teaches a device made from a plastic material including a metallic reinforcing insert completely embedded within the plastic material in order to reinforce the plastic material. Because both Geisser and Judd teach devices comprising reinforcing inserts for plastic materials, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one reinforcing insert with the other in order to achieve the predictable result of reinforcing the plastic material.

The device of Geisser and modified by Judd disclose the invention as claimed except for the insert being made from a shape memory material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Geisser as modified by Judd wherein the insert is made from a shape memory material, since it has been held to be within the general skill of a worker



in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

12. Claims 12, 13, 20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisser (U.S. Patent 5,454,815) in view of Morgan (U.S. Patent 5,910,106).

Geisser discloses a method comprising the steps of providing a body made from a plastic material including a carbon fiber reinforcing insert completely embedded within the plastic material, such as polyamides (column 3 lines 7-12), that come into contact with a bone to rasp the bone, wherein the plastic is hard enough to rasp the bone and wears out after a single use (column 1 lines 29-35; column 1 lines 40-67), wherein the plastic is inherently capable deteriorating when put into an autoclave set to at least 137 degrees Celsius. Geisser fails to disclose the method further comprising the step of exposing the device to gamma or beta radiation. Morgan teaches a method comprising the step of exposing a device to gamma radiation in order to sterilize the device (column 6 lines 10-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Geisser further comprising the step of exposing the device to gamma radiation in view of Morgan in order to sterilize the device.

13. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Howard (U.S. Patent 5,817,097) in view of Geisser (U.S. Patent 5,454,815) and Morgan (U.S. Patent 5,910,106).

Howard discloses a device comprising a body made from a plastic material (column 4 lines 50-54) that contacts the bone that is to be removed, wherein the plastic is hard enough to withstand removal of the bone. Howard fails to disclose the device being made from specific plastic materials, such as polyamides, and the device being exposed to gamma radiation. Geisser teaches a device comprising a body made from a known plastic material, such as polyamides, in order to provide a cost effective, i.e. cheap, device to manufacture. Morgan teaches a device exposed to gamma radiation in order to sterilize the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Howard wherein the body is made from a plastic material, such as polyamides, in view of Geisser and to expose the device to gamma radiation in view of Morgan in order to provide a cost effective device to manufacture and to sterilize the device.

Regarding the device being capable of deteriorating in an autoclave at a temperature of at least 137 degrees Celsius, the device of Howard as modified by Geisser and Morgan is inherently capable of deteriorating in an autoclave at a temperature of at least 137 degrees Celsius, since this is nothing more than a property of the polyamide plastic material.

14. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Temeles (U.S. 6,283,971) in view of Geisser (U.S. Patent 5,454,815) and Morgan (U.S. Patent 5,910,106).

Temeles discloses a device comprising a hemispherical head made from a plastic material (column 3 lines 22-23) and at least one blade in the shape of a rib

embedded within and protruding from the head for attacking/cutting bone. Temeles fails to disclose the head being made from specific plastic materials, such as polyamides, the plastic being exposed to gamma radiation, and the at least one blade being made from metal. Geisser teaches a device comprising a body made from a known plastic material, such as polyamides, in order to provide a cost effective, i.e. cheap, device to manufacture. Morgan teaches a device exposed to gamma radiation in order to sterilize the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Howard wherein the body is made from a plastic material, such as polyamides, in view of Geisser and to expose the device to gamma radiation in view of Morgan in order to provide a cost effective device to manufacture and to sterilize the device. Regarding the at least one blade being made from metal, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Temeles with metallic blades, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

### ***Response to Arguments***

15. Applicant's arguments filed 08/04/2008 have been fully considered but they are not persuasive. The applicant's argument that Geisser does not disclose a device being made from a plastic material inherently capable of being melted at a temperature of at least 137 degrees of Celsius is not persuasive. The examiner responded to this argument above in the rejection. The applicant's argument that Geisser does not

disclose a device that wears out after a single use is not persuasive. The examiner responded to this argument above in the rejection. The applicant's argument that Judd is not analogous art is not persuasive. First, the examiner would like to note that Geisser discloses a device made from plastic material including a reinforcing insert, i.e. the carbon fibers, and Judd discloses a device made from plastic material including a reinforcing insert, i.e. perforated metallic insert. Because both references disclose reinforcing inserts for plastic materials the references are analogous.

### ***Conclusion***

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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